

Liquid Chromatograph

Flexar Analytical / FX-10 UHPLC Pumps

Installation Qualification (IQ) and Operational Qualification (OQ)

Company Name:	Template-Company
Address:	Template-Address
Location, Room:	
Serial Number or System Name:	Template-SN
Protocol Number:	Template-Protocol
Issue Date:	27 May 2009
Date Tested: Valid if tested within 1 year of Issue Date	
Recertification Period	Recommended at 12 Months
Recertification Due Date:	

Release History

Part Number	Release	Publication Date
09234069	D	June 2009

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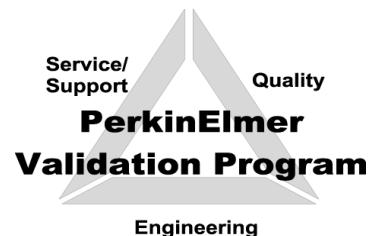


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Introduction

Objective

The objective of this document is to detail the environmental and facilities requirements necessary for proper installation and operation of the Flexar Analytical / / FX-10 UHPLC Pump. The completed process demonstrates that the equipment meets the vendor-developed standards of operation and safety, and performs the functions specified by the manufacturer.

Scope and Responsibility

PerkinElmer is responsible for providing trained personnel, the IQ/OQ elements outlined in this plan and verifying that these elements are fully executed and documented.

Template-Company is responsible for accepting the terms of this plan and providing the facility with all environmental requirements for the proper installation of the Flexar Analytical / / FX-10 UHPLC Pump.

Template-Company is responsible for providing personnel and assistance to PerkinElmer for implementing the IQ/OQ outlined in this document.

Warranty Period and Service

Full details of PerkinElmer's instrument warranty have previously been provided with quotations, order acknowledgements and invoices. PerkinElmer's instrument warranty covers all parts and labor, but excludes consumable materials. Exceptions may apply to instruments purchased used.

Contact your PerkinElmer service provider for a service plan which may be purchased to extend coverage beyond warranty. PerkinElmer recommends contracting regular preventive maintenance. Over time, failure to perform the recommended preventive maintenance may reduce the reliability of some systems.

Need to Re-Qualify

The instrument may need to qualified again following modifications made to the original configuration or if the instrument is serviced or moved.

Notices

Except as specifically set forth in its terms and conditions of sale, PerkinElmer makes no warranty of any kind with regard to this document, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

PerkinElmer shall not be liable for incidental or consequential damages in connection with the furnishing or use of this document.

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Protocol Documentation

Documentation protocol may be superseded by customer SOP

Writing Instruments

All writing will be done with a black or blue ink pen.

Signatures

A signature of each party involved with the ownership, management, testing, and quality assurance of each instrument will be required before testing will proceed and for final approval at completion.

On any page where a written entry is made, or data is gathered by a PerkinElmer representative, that page must be signed and dated by the PerkinElmer representative.

Up to three signature entries are provided each for Customer and PerkinElmer on the Preliminary Report Approval Page and Final Approval Page. If any signature lines are unused, draw a single diagonal line filling the Signature area and then write initials and date next to the line.

All signatures will be the signer's full legal name as legibly as can be written and dated.

Initials

At any point when initials are to be used, they will contain at least two of the initials and include a date.

Date

Dates will be given in the format of DD-MMM-YYYY. If a month or date is only one digit, a zero will be employed to maintain the two-digit format for each entry.

Error Codes

When an error is corrected, a single horizontal line through the error will be used. The line will then be initialed and dated along with an error code from the list found in the protocol.

Spaces

For columns where the protocol is asking whether something has been verified, a "Yes" will be written. If not, a "No" will be written and an explanation will be stated in the Comments section. A check mark or "N" is unacceptable. "NA" may be used where the verification was not applicable.

Pass/Fail

For areas where the protocol requires a "Pass/Fail", the words "Pass" or "Fail" will be written in. If the instrument passes, Pass will be entered. If the instrument fails, Fail will be entered.

Visual Inspections

All visual inspections will be filled out with a word that indicates the physical condition being observed. If no damage is observed, use the word "None" if no damage is present. If damage is observed, write a description of the damage observed. This will apply to any visual inspections.

Calibration/Expiration dates

MM/YY format will be used to denote calibration and reagent expiration dates. The instrument or reagent is valid until the last day of the month noted.

Temperature

All temperatures will be given in the unit of Celsius (°C)

Blank Areas

If there are no comments for a "Comments" section, "None" is written and the rest of the lines are left blank. If a section is not applicable, such as an alarm function, "NA" is sufficient.

Once an entry has been made (other than "None") any remaining space in the Comments (either single or multiple blank lines) requires a single diagonal line filling the area, along with initials and date next to the line.

EXCEPTION: DO NOT cross out blank lines on the "Error Code Abbreviation, Definition and Making Corrections" page. These pages or sections are either copied for future documentation needs or provide space to maintain records into the future.

Acceptance Criteria

All tests must include values for acceptance criteria and the results of that test must be included.

Precision and Accuracy Measurements

The following areas of precision and accuracy will be noted on a per-test basis.

All instrument precision values (when available) will be noted within the OQ document. All data entered into the OQ document will reflect these values.

For example: If a precision value of four significant digits is supplied for a test by the manufacturer, then all four digits will be entered with the last digit being rounded down if the fifth digit is below 5, rounded up if above 5, and rounded up if fifth digit is 5.

Failure Mode Responses

If a test result is determined to be outside of the precision parameters set forth by manufacturer of instrument, it will be discussed with the customer first and if agreed both by customer and PerkinElmer then it will be repeated a second time to confirm the result. If the second result fails, the instrument owner will be contacted to discuss a reasonable course of action. If however, the second test passes, a note will be made as to the reason for the primary failure and the second test data will be used.

Test -> Fail -> Repeat -> PASS -> Report 2nd result

Deviation

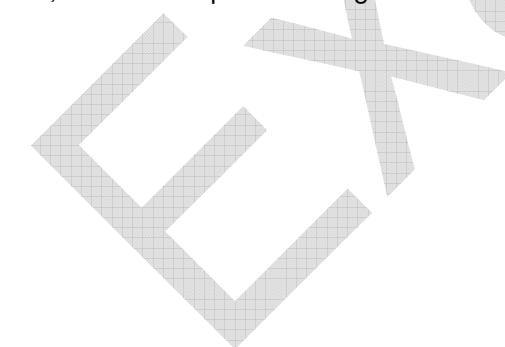
Deviations are events that are a departure from the specific protocol procedures as they were approved.

Deviations to the plan are permitted if those deviations are clearly detailed, approved by all parties and entered in Appendix - Deviations

Change Control

Change control procedures are in place to maintain the validation process after modifications are made to the original configuration. Any changes to the hardware, firmware or software of a validated system must be clearly specified and the validation confirmed and recorded.

1. A blank Change Control form is located in Appendix C. Consider making photocopies when blank.
2. If used, insert a completed Change Control Form and its associated data as an Attachment.



Error Code Abbreviation, Definition, and Making Correction

The error code abbreviation and definition list below is provided for clients and reviewers to make necessary entries and corrections after the document has been approved.

PerkinElmer technical staff and reviewers make all necessary efforts to ensure that this document and related attachments are free of errors and mistakes. However, some typographical, formatting, and inadvertently erroneous entries may exist within the document that can be corrected by client(s). Once an error is found, (1) simply strike the erroneous word or entry with a black pen, (2) enter the correct word or entry above the erroneous word or entry, (3) enter the code (for example; IE for incorrect entry), and (4) then initial and date.

Space is also provided to create new codes or to enter the codes used and recommended by your compliance department.

CE	Calculation Error
IE	Incorrect Entry
IM	Instrument Malfunction
IO	Inadvertently Omitted
IR	Instrument Recalibrated
LE	Late Entry (of initials or date)

NA	Not Applicable
SE	Spelling Error
TE	Transcription Error
TYP	Typographical Error
WD	Wrong Date Entered
WO	Writeover

Additional Codes

Code	Definition	Initials	Date

Approval Page

Preliminary Protocol Approval

This is to certify that the Installation Qualification and Operational Qualifications procedures for the Flexar Analytical / / FX-10 UHPLC Pump **Serial number Template-SN** have been reviewed and both PerkinElmer LAS and Template-Company have agreed to proceed with the procedures described in this document.

Template-Company			
Signature	Name	Title	Date

PerkinElmer LAS			
Signature	Name	Title	Date

Final Approval

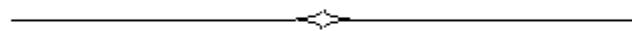
This is to certify that the Installation Qualification and Operational Qualifications procedures for the Flexar Analytical / / FX-10 UHPLC Pump **Serial number Template-SN** have been performed and the configuration installed **meets** [] **does not meet** [] the procedures and specifications described in this document.

Template-Company			
Signature	Name	Title	Date

PerkinElmer LAS			
Signature	Name	Title	Date

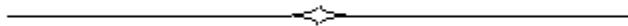
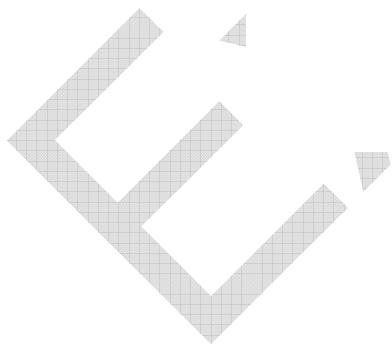
sample

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EE

Part I – Installation Qualification



1.1 System Summary

1.1.1 Instrument Identification

Manufacturer	PerkinElmer
Model	Flexar Analytical / FX-10 UHPLC Pump
Equipment Serial #	Template-SN
Firmware Version	
Instrument Control Software Version	
Model options, circle as applicable	Isocratic / Binary / Quaternary / FX-10

1.1.2 Specifications

Refer to respective documents for specifications like Voltage requirements, Line Frequency, Power Consumption, Temperature, Relative Humidity, etc.

Refer to respective documents for minimum PC requirements.

1.1.3 Location Requirements

Refer to respective documents for specific requirements for the location of the instrument. Requirements are typically, space (actual size, bench space and weight requirements especially if heavy), environment, power supply, gas supply, etc., and any other needs for the safe and consistent operation of the instrument.

1.1.4 Maintenance and Troubleshooting

Routine maintenance can be performed by a trained analyst using the instructions found in the respective documents for maintenance and troubleshooting. PerkinElmer has trained service representatives, who perform other planned maintenance service annually or as required. Departmental Standard Operating Procedures (SOPs) shall also be consulted to implement and document the necessary repairs.

1.1.5 Hazards and Safety Precautions

Refer to respective documents for the safety summary outlines and explanation.

Comments:

PerkinElmer LAS Representative:

Date:

Reviewed By:

Date:

Flexar Analytical / FX-10 UHPLC Pumps IQ/OQ Rev. D June 2009

1.2 Documentation

1.2.1 Equipment Manual

Part No.	Title
	Flexar Analytical / FX-10 UHPLC Pump User's Guide

1.2.2 Purchase Order Certification

The Flexar Analytical / FX-10 UHPLC Pump Template-SN is in compliance with the specifications of the purchase order.

Purchase Order Number	Template-PO
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1.2.3 PerkinElmer Service Engineer Training

Persons authorized by PerkinElmer LAS to perform validations have been properly trained. Training is documented, and a certificate is issued by PerkinElmer LAS to that effect.

See Attachment #1 for PerkinElmer LAS Training Certificate.

1.3 Installation Qualification

Verify the following list and mark as appropriate:

	Description	Verified
1.3.1	The working environment is suitable with reference to the appropriate section in the user's manual	
1.3.2	The correct basic equipment has been provided in accordance with the purchase order	
1.3.3	The packaging is undamaged	
1.3.4	The instrument, PC and other supplied equipment are undamaged	
1.3.5	Users Guide is identified	
1.3.6	Manufacturer's specifications included in manual	
1.3.7	The power requirement settings of the instrument, PC etc., are compatible with those of the working environment. <i>Note: It is the responsibility of Template-Company to ensure proper voltage / current / frequency of the electrical line supplied for operating the Flexar Analytical / FX-10 UHPLC Pump.</i>	
1.3.8	Adequate room for ventilation and servicing the equipment	

Comments:

PerkinElmer LAS Representative: _____ Date: _____

Reviewed By: _____ Date: _____

1.3.9	PC's requirements are met with reference to the appropriate section in the user's guide.	
1.3.10	Instrument is identified, connected and set up in accordance with reference to the appropriate instructions in the user's guide.	
1.3.11	Adequate electricity supply available and unit is grounded	
1.3.12	Software installed on the PC with reference to the appropriate instructions in the user's guide.	
1.3.13	Necessary components/accessories installed with reference to the appropriate instructions in the user's guide.	
1.3.14	Firmware verification	
1.3.15	Software installed and appropriate panels displayed:	
1.3.16	Instrument control software installed if applicable	
1.3.17	Data Acquisition Software installed	
1.3.18	Operating System (name and version)	
1.3.19	Other Software installed if applicable (name and version)	
1.3.20	Start-up diagnostics run to completion (instrument initialized)	
1.3.21	Warranty and available services explained	
1.3.22	System Familiarization and Orientation Completed	
1.3.23	List Attendees:	

1.4 Installation Qualification Verification

The Flexar Analytical / FX-10 UHPLC Pump, Serial Number Template-SN, has been properly set up and installed, and all appropriate forms and documents supporting the system have been filled out and are available.

Verified:

Comments:

PerkinElmer LAS Representative:

Date:

Reviewed By:

Date:

Part II – Operational Qualification

Excl!

2.1 Operating Procedure References

2.1.1 Standard Operating Procedures pertaining to the Flexar Analytical / FX-10 UHPLC Pump

It is responsibility of the customer to follow a SOP for use of the equipment to ensure consistent operations. The customer SOP may be written after the Qualification and can be added as an attachment after PerkinElmer completes this IQ/OQ.

2.2 Operational Qualification Instruction

The following instructions apply to the **Operational Qualification Test Description**

2.2.1	Record Model (or Part Number) and Serial Number of any accessories or components not covered in the OQ
2.2.2	Record the Serial Number and Calibration Date for each item of Test Equipment used.
2.2.3	Record the Batch/Lot Number and Expiration Date of each Standard, Reagent and Solvent used, including those supplied by the customer.
2.2.4	Label all solutions prepared at customer site in accordance with the customer requirements (date, content, expires by, etc)
2.2.5	Provide the Standard certificates as Attachments.

The following instructions apply to the **Parameter Testing**

2.2.6	Conduct Parameter Testing and record test data, Pass/Fail and Comments.
2.2.7	Verify the completed OQ in Section 2.5
2.2.8	Sign, date and number attachments of all recordings or printouts made during the test procedure (ex. settings, spectrograms).
2.2.9	Fill in All Appendices, as required.
2.2.10	Complete and sign off the Final Approval
2.2.11	Complete and affix an IQ/OQ Certification Sticker to the instrument.

Comments:

PerkinElmer LAS Representative:

Date:

Reviewed By:

Date:

2.3 Operational Qualification Test Description

Configurations Covered	Flexar Analytical/ FX-10 UHPLC Pump			
Accessories/Components not covered	Model	Serial Number		
Estimated Certificate Testing Time				
Pre-test Stabilization	N/A			
Testing Time	2.0 Hours			
Materials Required				
Documentation	Part Number			
Pump Users Manual (Not needed for testing. Reference only)				
Pump Service Manual (Not needed for testing. Reference only)				
IQ/OQ Certification Sticker	09934512			
Test Equipment	Manufacturer	Model	Serial Number	Calibration Due Date
Restrictor Coil	PerkinElmer	02540843	N/A	N/A
1000 PSI Back Pressure Regulator	PerkinElmer	N2910381	N/A	N/A
Calibrated Scale or Balance				
Calibrated Timing Device				
Customer Supplied	Manufacturer	Part Number	Batch/Lot	Expiration
H2O	N/A	N/A		
Acetone				

All solutions prepared at customer site must be labeled in accordance with the customer requirements

Tests	
Name of Test	Description

Comments:

PerkinElmer LAS Representative:	Date:
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Reviewed By:	Date:
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Pressure Pulsations	Pulsations (PSI) at 1 ml/min solvent flow and 1000 PSI backpressure (approx)
Flow Accuracy	For Analytical pumps, solvent flow as measured at 1ml and 3ml per minute. For the FX-10 UHPLC pumps, solvent flow as measured at 0.3ml and 0.9ml per minute.
Compositional Accuracy	For Binary / Quaternary Analytical pumps, accuracy as measured by relative UV absorbance (265 nm) at programmed proportions of 0.2% Acetone/Water and Water alone.

PerkinElmer assumes no responsibility for test results.

2.4 Parameter Testing:

2.4.1 Pressure Pulsations Test

Test Conditions

Comments:

PerkinElmer LAS Representative:

Date:

Reviewed By:

Date:

Flexar Analytical / FX-10 UHPLC Pump IQ/OQ Rev. D June 2009

- The Pressure Pulsations Test is to verify that the output flow fluctuations are within specification. The specification for this test to pass is 2 % peak-to-peak of the running pressure at which the test is run.

Test Prerequisites

- Start the pump and let the pressure stabilize

Test Steps

- Connect the pump output to a restrictor coil or 1000 psi backpressure device. Set the pump flow rate to 1 mL/min. Running pressure for this test must be more than 500 psi. Adjust tubing length as required to obtain the required back pressure.
- Monitor the displayed pressure readout for 1 minute. Note the observed maximum and minimum pressures.
- Using the numbers obtained determine:
 1. The difference between maximum and minimum (Delta).
 2. The value of the mid-point pressure (MP).
 3. The 2% value of the midpoint pressure. This mid-point value is the pressure used to compute what the 2 % peak-to-peak error band should be.

Example:

Max 1020 psi, **Min** 1003 psi, **Mid Point** (MP Pressure) = 1011 psi.

2 % MP = MP * 0.02 = 20.22 psi

Observed Delta = 17 psi

Spec = Observed Delta <= 2 % MP

2.4.1 Test Results

Parameter	Specification	Min Psi	Max Psi	Delta	MP	Pass/Fail	Comments
Pressure Fluctuation	\leq 2% of MP PSI						

2.4.2 Analytical Pump (100 μ L Piston) Flow Check @ 1 mL/min

Test Conditions

- Chromatographic Conditions: 100 % H₂O
1 mL/min

Test Prerequisites

Comments:	
PerkinElmer LAS Representative:	Date:
Reviewed By:	Date:
Flexar Analytical / FX-10 UHPLC Pump IQ/OQ Rev. D June 2009	

- It is important that the volume delivered is correct; the pressure during the delivery is not critical. There is a minimum pressure requirement of 350 psi for the check valves to operate properly.

Test Steps

- Connect the backpressure regulator to the output of the pump. This device will create the necessary back pressure on the pump check valves.
- Purge the pump and fill the solvent line to be used for the test with water.
- Zero the scale. Weigh the collection vessel on a calibrated scale or balance.
- Take the collection vessel and go to the pump and set the pump flow for 1 mL/minute.
- Start the pump. (Direct the initial flow of water off to waste until the pressure stabilizes.
- When pressure stabilizes, direct the flow of water into the collection vessel and simultaneously start a stopwatch or other timing device.
- Let the pump run for 5 minutes.
- When 5 minutes has elapsed, remove the tube from above the collection vessel and insert it into the waste.
- Weigh the collection vessel with the water. Subtract the weight of the collection vessel.
- The remaining weight of the water should be 5 grams ± 0.05 g (40.95 to 5.05 g)
 $1 \text{ mL/min} * 5 \text{ min} = 5 \text{ g}$ (water weighs 1 gram per mL)
- Divide the weight of the water by 5 to get the volume delivered in a 1 minute interval.
- Record this number in the Test Result field of Flow Accuracy @ 1 mL/min portion of the IQOQ Test Certificate. Enter N/A if testing FX-10 UHPLC Pump.

2.4.2 Test Results

Parameter	Specification	Test Result	Pass/Fail	Comments
Analytical Pump (100 μL Piston) Accuracy: 1 mL/min	$\pm 1\%$ of 1mL/min (0.99ml/min to 1.01ml/min)			

2.4.3 Analytical Pump (100 μL Piston) Flow Check @ 3 mL/min

Test Conditions

- Chromatographic Conditions: 100 % H_2O
3 mL/min

Test Prerequisites

- It is important that the volume delivered is correct; the pressure during the delivery is not critical. There is a minimum pressure requirement of 350 psi for the check valves to operate properly.

Comments:

PerkinElmer LAS Representative:

Date:

Reviewed By:

Date:

Test Steps

- Connect the backpressure regulator to the output of the pump. This device will create the necessary back pressure on the pump check valves.
- Purge the pump and fill the line to be used for the test with water.
- Zero the scale. Weigh the collection vessel on a calibrated scale or balance.
- Take the collection vessel and go to the pump and set the pump flow for 3 mL/minute.
- Start the pump. (Direct the initial flow of water off to waste until the pressure stabilizes.
- When pressure stabilizes, direct the flow of water into the collection vessel and simultaneously start a stopwatch or other timing device.
- Let the pump run for 5 minutes.
- When 5 minutes has elapsed, remove the tube from above the collection vessel and insert it into the waste.
- Weigh the collection vessel with the water. Subtract the weight of the collection vessel.
- The remaining weight of the water should be 15 grams ± 0.15 g (14.85 to 15.15 g)
 $3 \text{ mL/min} * 5 \text{ min} = 15 \text{ g}$ (water weighs 1 gram per mL)
- Divide the weight of the water by 5 to get the volume delivered in a 1 minute interval.
- Record this number in the Test Result field of Flow Accuracy @ 3 mL/min portion of the IQ/OQ Test Certificate. Enter N/A if testing FX-10 UHPLC Pump.

2.4.3 Test Results

Parameter	Specification	Test Result	Pass/Fail	Comments
Analytical Pump (100 μL Piston) Accuracy: 3 mL/min	$\pm 1\%$ of 3mL/min (2.97mL/min to 3.03mL/min)			

2.4.4 FX-10 UHPLC Pump (30 μL Piston) Flow Check @ 0.3 mL/min

Test Conditions

- Chromatographic Conditions: 100 % H_2O
0.3 mL/min

Test Prerequisites

- It is important that the volume delivered is correct; the pressure during the delivery is not critical. There is a minimum pressure requirement of 350 psi for the check valves to operate properly.

Comments:

PerkinElmer LAS Representative:

Date:

Reviewed By:

Date:

Test Steps

- Connect the backpressure regulator to the output of the pump. This device will create the necessary back pressure on the pump check valves.
- Purge the pump and fill the line to be used for the test with water.
- Zero the scale. Weigh the collection vessel on a calibrated scale or balance.
- Take the collection vessel and go to the pump and set the pump flow for 0.3 mL/minute.
- Start the pump. (Direct the initial flow of water off to waste until the pressure stabilizes.
- When pressure stabilizes, direct the flow of water into the collection vessel and simultaneously start a stopwatch or other timing device.
- Let the pump run for 10 minutes.
- When 10 minutes has elapsed, remove the tube from above the collection vessel and insert it into the waste.
- Weigh the collection vessel with the water. Subtract the weight of the collection vessel.
- The remaining weight of the water should be 3 grams ± 0.03 g (2.97 to 3.03 g)
 $0.3 \text{ mL/min} * 10 \text{ min} = 3 \text{ g}$ (water weighs 1 gram per mL)
- Divide the weight of the water by 10 to get the volume delivered in a 1 minute interval.
- Record this number in the Test Result field of Flow Accuracy @ 0.3 mL/min portion of the IQ/OQ Test Certificate. Enter N/A if testing Analytical Pump.

2.4.4 Test Results

Parameter	Specification	Test Result	Pass/Fail	Comments
FX-10 Pump (30 μL Piston) Accuracy: 0.3 mL/min	$\pm 1\%$ of 0.3mL/min (0.297ml/min to 0.303ml/min)			

2.4.5 FX-10 UHPLC Pump (30 μL Piston) Flow Check @ 0.9 mL/min

Test Conditions

- Chromatographic Conditions: 100 % H_2O
0.9 mL/min

Test Prerequisites

- It is important that the volume delivered is correct; the pressure during the delivery is not critical. There is a minimum pressure requirement of 350 psi for the check valves to operate properly.
- Test Steps
- Connect the backpressure regulator to the output of the pump. This device will create the necessary back pressure on the pump check valves.

Comments:

PerkinElmer LAS Representative:

Date:

Reviewed By:

Date:

- Purge the pump and fill the line to be used for the test with water.
- Zero the scale. Weigh the collection vessel on a calibrated scale or balance.
- Take the collection vessel and go to the pump and set the pump flow for 0.9 mL/minute.
- Start the pump. (Direct the initial flow of water off to waste until the pressure stabilizes.
- When pressure stabilizes, direct the flow of water into the collection vessel and simultaneously start a stopwatch or other timing device.
- Let the pump run for 10minutes.
- When 10minutes has elapsed, remove the tube from above the collection vessel and insert it into the waste.
- Weigh the collection vessel with the water. Subtract the weight of the collection vessel
- The remaining weight of the water should be 9 grams ± 0.09 g (8.91 to 9.09g)
 $0.9 \text{ mL/min} * 10 \text{ min} = 9 \text{ g}$ (water weighs 1 gram per mL)
- Divide the weight of the water by 10 to get the volume delivered in a 1 minute interval.
- Record this number in the Test Result field of Flow Accuracy @ 0.9 mL/min portion of the IQOQ Test Certificate. Enter N/A if testing Analytical Pump

2.4.5 Test Results

Parameter	Specification	Test Result	Pass/Fail	Comments
FX-10 Pump (30 μ L Piston) Accuracy: 0.9 mL/min	$\pm 1\%$ of 0.9 mL/min (0.891mL/min to 0.909mL/min)			

Comments:	
PerkinElmer LAS Representative:	Date:
Reviewed By:	Date:
Flexar Analytical / FX-10 UHPLC Pump IQ/OQ Rev. D June 2009	

2.4.6 Binary / Quaternary Analytical Pump Composition Accuracy Test

Test Prerequisites

There is a minimum pressure requirement of 350 psi for the check valves to operate properly. To ensure the valves are operating and seating during the test PerkinElmer runs the test with the pressure approximately >500 psi. This is accomplished by using a length of 0.007" ID tubing or a backpressure device that will create the necessary back pressure on the check valves.

Test Conditions

The Composition Accuracy Test proves that the proportioning valves are operating correctly. This is accomplished by varying the amounts of solvent entering the pump through the proportioning valves. Using an acetone solution, which has an absorbance at 265 nm as one solvent, and water, which does not absorb at 265 nm we look at the absorbance of the resulting composition. By controlling or proportioning the amount of acetone in the water/acetone composition we can change the absorbance of the mobile phase composition. We do this by setting up a pump program to run through several different positions of the proportioning valves and measure the absorbance of the resultant mobile phase.

Test Steps

- Connect pump output directly to the backpressure regulator or other device (length of tubing for example) to create the necessary back pressure.
- Fill reservoirs A (and C if testing a quaternary model) with HPLC grade water.
- Pipette 1.0 mL of acetone into approximately 250 mL of HPLC-grade water. Dilute to 500 mL with HPLC grade water. Transfer the mobile phase to the labeled solvent reservoirs. Place the 0.2% acetone solution into reservoirs B (and D if testing a quaternary model).
- Ensure that acetone solution is mixed well and degassed.
- Bypass the column and autosampler and connect pump output directly to the backpressure regulator or other device (length of tubing for example) to create the necessary back pressure.
- Connect the output of the back pressure device to the input of the detector flowcell.
- Equilibrate and insure the binary or quaternary valves are operating correctly by running the pumps as follows:
 - Binary pump - run 50/50 at 5mL/min for 10 minutes
 - Quaternary pump - run 25/25/25/25 at 5 mL/min for 10 minutes.
- Observe the P-counts on the pump (CNFG/CAL/TEST/PCNT). The P-count value should fall typically in the range of 1300 ± 50 . Stability is important and the Range value should be typically less than 12.
- Set the detector wavelength to 265 nm.
- Set the flow rate to 5 mL/minute from reservoir A and allow the pressure to stabilize. Ensure the pump and baseline is stable at 5 mL/min.
- Create and run the method in Tables 1 and 2 as appropriate with TotalChrom® or Chromera®, zeroing the detector at the end of step zero. Step 2 is the 100% reference.

- Record mV or absorbance values from the run for each step (AU1 through AU6, and if applicable, for the quaternary pump, AU7 through AU10) in the AU column of Tables 1 and 2 below.

Table 1 - Binary and Quaternary (Reservoirs A and B)

STEP	TIME	FLOW	%A (water)	%B (acetone)	CURV	AU (absorbance or mV)
0	5.0	5.0	100	0	0.0	
1	1.0	5.0	100	0	0.0	
2	3.0	5.0	0	100	0.0	AU1 =
3	3.0	5.0	10	90	0.0	AU2 =
4	3.0	5.0	49	51	0.0	AU3 =
5	3.0	5.0	51	49	0.0	AU4 =
6	3.0	5.0	90	10	0.0	AU5 =
7	5.0	5.0	100	0	0.0	AU6 =

Table 2 - Quaternary (Reservoirs C and D)

STEP	TIME	FLOW	%C (water)	%D (acetone)	CURV	AU (absorbance or mV)
0	5.0	5.0	100	0	0.0	
1	1.0	5.0	100	0	0.0	
2	3.0	5.0	0	100	0.0	AU7 =
3	3.0	5.0	10	90	0.0	AU8 =
4	3.0	5.0	90	10	0.0	AU9 =
5	5.0	5.0	100	0	0.0	AU10 =

Comments:

PerkinElmer LAS Representative:

Date:

Reviewed By:

Date:

2.4.7 Test Results

PARAMETER	SPECIFICATION	TEST RESULT	PASS/FAIL
Composition Accuracy	Within $\pm 1.0\%$ absolute @ 5 mL/min		
Channel A and B	% Solvent B		
	10%		
	49%		
	51%		
	90%		
49 / 51 Delta Range	Between 1.5% and 2.5%		
Channel C and D	% Solvent D		
	10%		
	90%		
Comments:			

2.5 Operational Qualification Verification

The Flexar Analytical / FX-10 UHPLC Pump, Serial Number Template-SN, operates and performs according to the stated Operational Qualification, and all appropriate forms and documents supporting the system have been filled out and are available.

Verified:

Comments:

PerkinElmer LAS Representative:

Date:

Reviewed By:

Date:

Part III – Appendices

Exhibit

Appendix A– Deviations

Describe in detail any deviation from the standard IQ/OQ. The deviation must be approved by **Template-Company** representative. If there is no deviation, no signature or date entry is required by **Template-Company** representative (enter NA for signature and then date). If there are no deviations, the PerkinElmer representative should enter "None" below and then sign and date.

Template

Template-Company Representative			
Signature	Name	Title	Date

PerkinElmer LAS Representative

Signature	Name	Title	Date

Appendix B– Change Control

Note: Create copies of this page, leaving original blank. Read instructions below.

Change Control procedures maintain the validation processes after modifications are made to the original configuration (by OEM, Template-Company, or PerkinElmer LAS).

The Change Control Form is located in Appendix B– Change Control and instructions are located in the Introduction. Insert the completed Change Control Form and its data into this validation document as an Attachment.

Change Control Revision Attachment #: _____

Component / Software Changed

Reasoning and Justification for Change

Verification of New Component / Software

Acceptance Criteria Used

Results of Verification (Attach original data)

Validation Results

Validation	Pass/Fail
Signature	Date
Performed By:	
Approved By:	

Appendix C– Attachments List

In the table below enter: each attachment; total pages for each attachment; company (OEM, Template-Company, or PerkinElmer). Sign and date. Entries for up to 20 Attachments are available. Additionally, label each page of each Attachment as follows:

- Attachment Number (as per this table)
- Page X of Y (total) Pages of the Attachment
- Initials of Reviewer
- Date

#	Description	# Pgs	Company	Signature	Date
1	PerkinElmer Service Engineer Training Certificate		PerkinElmer		
2	Certificate of Conformity				
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
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19					
20					

Appendix D- Document History

Appendix E- Spine Label for Instrument / System Log Book

Cut out the label below and insert into the spine of the Instrument / System Log Book, then destroy the remainder of this page as it is no longer required.

Instrument / System Log Book

Template-Company

Model

Serial Number

Protocol ID

Flexar Analytical / FX-10 UHPLC Pump

Template-SN

Protocol ID

Template-Protocol

